8. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding bromoform and dibromochloromethane in air, water, and other media are summarized in Table 8-1.

An acute-duration oral MRL of 0.7 mg/kg/day has been derived for bromoform. This MRL is based on a NOAEL of 72 mg/kg/day and a LOAEL of 145 mg/kg/day for centrilobular pallor in mice receiving gavage doses of bromoform for 14 days (Condie et al. 1983). The MRL was derived by dividing the NOAEL by an uncertainty factor of 100 (10 for animal to human extrapolation and 10 for human variability).

An intermediate-duration oral MRL of 0.2 mg/kg/day has been derived for bromoform. This MRL is based on a NOAEL of 50 mg/kg for hepatocellular vacuolization in rats administered gavage doses of bromoform in corn oil 5 days/week for 13 weeks (NTP 1989a). The MRL was derived by dividing the duration adjusted NOAEL of 18 mg/kg/day by an uncertainty factor of 100 (10 for animal to human extrapolation and 10 for human variability).

A chronic-duration oral MRL of 0.2 mg/kg/day has been derived for bromoform. This MRL is based on a LOAEL of 100 mg/kg for hepatocellular vacuolization in rats administered gavage doses of bromoform in corn oil 5 days/week for 2 years (NTP 1989a). The MRL was derived by dividing the duration adjusted LOAEL of 71 mg/kg/day by an uncertainty factor of 300 (3 for use of a minimal LOAEL, 10 for animal to human extrapolation, and 10 for human variability).

An acute-duration oral MRL of 0.1 mg/kg/day has been derived for dibromochloromethane. This MRL is based on a LOAEL of 37 mg/kg for hepatocellular vacuolization in mice administered gavage doses of dibromochloromethane in corn oil for 14 days (Condie et al. 1983). The MRL was derived by dividing the LOAEL by an uncertainty factor of 300 (3 for use of a minimal LOAEL, 10 for animal to human extrapolation, and 10 for human variability).

A chronic-duration oral MRL of 0.09 mg/kg/day has been derived for dibromochloromethane. This MRL is based on a LOAEL of 40 mg/kg for fatty changes in the liver of rats administered gavage doses of dibromochloromethane in corn oil for 2 years (NTP 1985). The MRL was derived by dividing the duration-adjusted LOAEL of 28 mg/kg/day by an uncertainty factor of 300 (10 for use of a minimal LOAEL, 10 for animal to human extrapolation, and 10 for human variability).

Table 8-1. Regulations and Guidelines Applicable to Bromoform and Dibromochloromethane

Agency	Description	Information	Reference
INTERNATIONAL			
Guidelines:			
IARC	Carcinogenicity classification		IARC 1999a, 1999b
	Bromoform	Group 3[a]	
	Dibromochloromethane	Group 3[a]	
WHO	Drinking water guideline		WHO 1996
	Bromoform	100 mg/L	
	Dibromochloromethane	100 mg/L	
NATIONAL			
Regulations and Guidelines:			
a. Air:			
ACGIH	TLV (8-hour TWA)		ACGIH 2003
	Bromoform[b]	0.5 ppm	
NIOSH	REL (10-hour TWA)		NIOSH 2003
	Bromoform[c]	0.5 ppm	
	IDLH	850 ppm	
OSHA	PEL (8-hour TWA) for general industry		OSHA 2003a 29 CFR 1910.1000, Table Z-1
	Bromoform[d]	0.5 ppm	
	PEL (8-hour TWA) for construction industry		OSHA 2003c 29 CFR 1926.55, Appendix A
	Bromoform[d]	0.5 ppm	
	PEL (8-hour TWA) for shipyard industry		OSHA 2003b 29 CFR 1915.1000
	Bromoform[d]	0.5 ppm	
USC	Hazardous air pollutant	Bromoform	USC 2003
b. Water			
EPA	Drinking water health advisories		EPA 2002a, 2002b
	Bromoform		
	1-day (10-kg child)	5.0 mg/L	
	10-day (10-kg child)	2.0 mg/L	
	DWEL[e]	0.7 mg/L	
	10^{-4} Cancer risk[f]	0.4 mg/L	
	Dibromochloromethane		
	1-day (10-kg child)	6.0 mg/L	
	10-day (10-kg child)	6.0 mg/L	
	DWEL[e]	0.7 mg/L	
	Lifetime[g]	0.06 mg/L	
	10^{-4} Cancer risk[f]	0.04 mg/L	
	Effluent guidelines and standards; toxic pollutants pursuant to Section 307 (a)(1) of the Clean Water Act	Bromoform	EPA 2003c 40 CFR 401.15

Table 8-1. Regulations and Guidelines Applicable to Bromoform and Dibromochloromethane

Agency	Description	Information		Reference
NATIONAL *(cont.)*				
EPA	National primary drinking water regulations			EPA 2003f 40 CFR 141.12
	MCL for total trihalo methanes[h]	0.10 mg/L		
	Pollutants of initial focus in the Great Lakes Water Quality Initiative	Bromoform and dibromochloromethane		EPA 2003m 40 CFR 132, Table 6
c. Food				
FDA	Bottled drinking water allowable concentrations for total trihalomethanes[i]	0.10 mg/L		FDA 2003 21 CFR 165.110
d. Other				
ACGIH	Carcinogenicity classification	A3[j]		ACGIH 2003
EPA	Carcinogenicity classification			IRIS 2003a, 2003b
	Bromoform	B2[k]		
	Dibromochloromethane	C[l]		
	RfD			IRIS 2003a, 2003b
	Bromoform	$2.0x10^{-2}$ mg/kg/day		
	Dibromochloromethane	$2.0x10^{-2}$ mg/kg/day		
	Community right-to-know; release report; effective date of reporting			EPA 2003i 40 CFR 372.65
	Bromoform	01/01/87		
	Identification and listing of hazardous waste; hazardous waste number			EPA 2003d 40 CFR 261, Appendix VIII
	Bromoform	U225		
	Land disposal restrictions; universal treatment standards	Waste water (mg/L)	Non-waste water mg/kg)	EPA 2003e 40 CFR 268.48
	Bromoform	0.63	15	
	Dibromochloromethane	0.57	15	
	Municipal solid waste landfills; hazardous constituents	Suggested method	PQL (µg/L)	EPA 2003a 40 CFR 258, Appendix II
	Bromoform	8010	2	
		8021	15	
		8260	5	
	Dibromochloromethane	8010	1	
		8021	0.3	
		8260	5	

Table 8-1. Regulations and Guidelines Applicable to Bromoform and Dibromochloromethane

Agency	Description	Information		Reference
NATIONAL *(cont.)*				
	Reportable quantity of hazardous substance in accordance with Section 307 (a) of the Clean Water Act, Section 112 of RCRA, and Section 112 of the Clean Air Act			EPA 2003b 40 CFR 302.4
	Bromoform	100 pounds		
	Reportable quantity of hazardous substance in accordance with Section 112 of RCRA			EPA 2003b 40 CFR 302.4
	Dibromochloromethane	100 pounds		
	Standards for the management of specific hazardous waste and types of hazardous waste management facilities			EPA 2003g 40 CFR 266, Appendix V
		Risk specific doses ($\mu g/m^3$)		
	Bromoform	7.0×10^{-1}		
	Standards for owners or operators of hazardous waste TSD facilities; maximum concentration for groundwater protection			EPA 2003h 40 CFR 264, Appendix IX
		Suggested method	PQL (µg/L)	
	Bromoform	8010	2	
		8240	5	
	Dibromochloromethane	8010	1	
		8240	5	
	TSCA; chemical information rules	Effective date	Sunset date	EPA 2003k 40 CFR 712.30
	Bromoform	03/11/94	05/10/94	
	TSCA; health and safety data reporting	Effective date	Sunset date	EPA 2003j 40 CFR 716.120
	Bromoform	06/01/87	06/01/97	
	Dibromochloromethane	06/01/87	06/01/87	
	TSCA; identification of specific chemical substance and mixture testing requirements for			EPA 2003l 40 CFR 799.5055
	Bromoform	Hydrolysis testing		
STATE				
a. Air	No data			
b. Water				
Arizona	Drinking water guideline			HSDB 2003a, 2003b
	Bromoform	0.19 µg/L		
	Dibromochloromethane	0.19 µg/L		

Table 8-1. Regulations and Guidelines Applicable to Bromoform and Dibromochloromethane

Agency	Description	Information	Reference
STATE *(cont.)*			
Florida	Drinking water guideline		HSDB 2003a,
	Bromoform	4.0 µg/L	2003b
	Dibromochloromethane	1.0 µg/L	
Minnesota	Drinking water guideline		HSDB 2003a,
	Bromoform	40 µg/L	2003b
	Dibromochloromethane	10 µg/L	
New Hampshire	Drinking water guideline		HSDB 2003a
	Bromoform	4.0 µg/L	
Wisconsin	Drinking water guideline		HSDB 2003a,
	Bromoform	4.4 µg/L	2003b
	Dibromochloromethane	60 µg/L	
c. Food	No data		
d. Other	No data		

[a]Group 3: not classifiable as to its carcinogenicity to humans
[b]Skin notation: refers to the potential significant contribution to the overall exposure by the cutaneous route, including mucous membranes and the eyes, either by contact with vapors or, of probable greater significance, by direct skin contact with the substance.
[c]Skin designation: indicates the potential for dermal absorption; skin exposure should be prevented as necessary through the use of good work practices and gloves, coveralls, goggles, and other appropriate equipment.
[d]Skin designation
[e]DWEL: a lifetime exposure concentration protection of adverse, non-cancer health effects, that assumes all of the exposure to a contaminant is from drinking water.
[f]Lifetime: the concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects for a lifetime of exposure. The Lifetime HA is based on exposure of a 70-kg adult consuming 2 L water/day.
[g]10^{-2} Cancer risk: the concentration of a chemical in drinking water corresponding to an excess estimated lifetime cancer risk of 1 in 10,000.
[h]Total trihalomethanes (the sum of the concentrations of bromoform, dibromochloromethane, bromodichloromethane, and chloroform) applies to subpart H community water systems which serve a population of 10,000 people or more until December 31, 2001. This level applies to community water systems that use only groundwater not under the direct influence of surface water and serves a population of 10,000 people or more until December 31, 2003. Compliance with the MCL for total trihalomethanes is calculated pursuant to 40 CFR 141.30. After December 31, 2003, this section no longer applies.
[i]Total trihalomethanes: sum of the concentration in mg/L of the trihalomethane compounds (bromoform, dibromochloromethane, bromodichloromethane, and chloroform), rounded to two significant figures.
[j]A3: confirmed animal carcinogen with unknown relevance to humans
[k]B2: probable human carcinogen
[l]C: possible human carcinogen

ACGIH = American Conference of Governmental Industrial Hygienists; CFR = Code of Federal Regulations; DWEL = drinking water equivalent level; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; HSDB = Hazardous Substances Data Bank; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; MCL = maximum contaminant level; NIOSH = National Institute for Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; PQL = practical quantitation level; RCRA = Resource Conservation and Recovery Act; REL = recommended exposure limit; RfD = reference dose; TLV = threshold limit values; TSCA = Toxic Substances Control Act; TSD = treatment, storage, and disposal; TWA = time-weighted average; USC = United States Code; WHO = World Health Organization

The EPA (IRIS 2003a) assigned bromoform an oral reference dose (RfD) of $2.00x10^{-2}$ mg/kg/day with an uncertainty factor of 1,000 based on hepatic lesions in rats (NTP 1989a). The EPA (IRIS 2003b) assigned dibromochloromethane an oral RfD of $2.00x10^{-2}$ mg/kg/day with an uncertainty factor of 1,000 based on hepatic lesions in rats (NTP 1985).

The EPA has assigned the following weight-of-evidence classifications: bromoform is assigned a classification of B2 (probable human carcinogen) (IRIS 2003a); and dibromochloromethane is assigned a classification of C (possible human carcinogen) (IRIS 2003b).